

The true costs of hygienic design - A 360 degree approach to food safety in hygienic design and operations.

As today's food manufacturing industry becomes more specialised and complex so does the equipment used in the industry.

With an increasing complexity, global distribution chains and long shelf life requirements, the risk of potential problems and recalls also increase if the production equipment is not fit for purpose for the given specific food application.


Within the European Union 637 public recalls were related to pathogenic microorganisms in 2015, the same level as previous two years (RASFF annual report 2015). In addition to this, an unknown number of products are also stopped before reaching the market by in-house inspections and control.

Furthermore food manufacturers may occasionally struggle to comply with customer requirements on non-pathogenic bacteria or reduced shelf life due to high level of yeast or lacto bacteria in their products, which may result in alternative disposal and reduced income.

As shown in the figure the number of recalls related to microbiological problems only represents a small fraction of quality problems and the associated quality costs.



Ensuring that process equipment is “fit for purpose” is therefore more important than ever, as a contamination problem may come with a high price, not only for loss of brand reputation and recall costs a product recall but also the underlying costs such as extra analyses and production down-time for extra cleaning or re-fitting of the equipment. This is why early and timely focus in hygienic design is a must in all new projects and modifications.



When buying new process equipment it is essential to have a strong and good dialog with the equipment manufacturer is essential in not only matters such as capacity, costs and delivery time but also food and safety matters.

The equipment must comply with relevant legal requirements such as the Machine Directive including the appendix for hygienic design of food processing machinery (EN 1672:2) and Food Contact Material requirements based on product information. But just as important the equipment must be fit for use in operation and the intended food application, taking into consideration the production environment and the skills and experience of the staff who will be operating, cleaning and maintaining the equipment.

“Plan – do – check – act” within the project phase and production start-up

Before starting up on new projects it is always important to have the necessary skills and experience in the project group and a culture, which ensures feedback throughout the project from all relevant stakeholders, no matter where in the organization they may be. Remember that cleaning operator will usually have more experience in how and where product may get stuck in the equipment than the purchaser.

Apart from capacity, delivery time and costs, a number of production and product related information must be shared and discussed in the initial phase of the project, such as operational temperature (both for operation and cleaning), dry or wet environment, hours of operation and cleaning time. Product characteristics such as viscosity, pH, fat%, salt% and alcohol% also needs to be addressed to ensure the right materials and gaskets are chosen in order to comply with Food Contact Material regulation.

During the design and manufacturing of equipment, risk assessments and design reviews must be carried out and where possible the manufactured equipment should be inspected / tested before installation, e.g. welding inspection or riboflavin testing at the manufacture or visual inspection upon arrival at site. Furthermore a HACCP review of the new equipment and/or process must also be conducted by the food manufactures HACCP team according to food safety standards such as BRC, IFS and ISO22000 FSSC.

Once your equipment gets into operation there may be surprises both when aiming for the promised capacity and the right product characteristics; e.g. heating may be increased to stabilize the product with a risk of product burn requiring more cleaning, or recipes may have changed due to market trials affecting viscosity, salt or pH levels in the product. In such cases you need to react and address the changes so neither the product nor the equipment will suffer in the long run.

Can the equipment be cleaned and maintained as intended and are both food contact surfaces and non-food contact surfaces clean? If not, this also needs to be addressed – re-fitting or allowing for more time for cleaning or maintenance may be needed.

As mentioned in my earlier publication on [Cleaning and Hygiene Validation](#) e.g. conducting UV test after 3-12months of operation is an effective way to identify hidden corners or other problems during cleaning.

Environmental and Safety requirements

In the above-mentioned process environmental and safety requirements should also be taken into consideration. E.g. if a project is to be delivered in an area with limited fresh water resources or restrictions on water discharge such requirements must also be addressed and discussed early in the design phase.

Feedback loop

Feedback loop is important in all processes and essential to the project culture as no one in a project team will have 100% insight in or overview of everything, furthermore giving and receiving feedback is the only way to achieve continual improvement.

Examples of feedback loop within the project could be from installation to design at the equipment manufacture or from the cleaning operator to production manager and onwards to the manufacture. However feedback from other manufactures using similar equipment or from existing production on similar types of product is just as important to include – especially in the early stages of the design.

Where things may go wrong

We use an approved supplier who knows our business – Yes but is the supplier also well informed about your latest product, its characteristics, the production environment at site and the skills of the operators?

We have received a folder of certificates so no need for inspection prior to installation – First of all you must ensure they are the correct certificates, e.g. if you treat cream the food contact materials declaration certificates must say so and not refer to testing in water or alcohol. Secondly certificates are good but your own visual inspection may identify damages during transport and delivery.

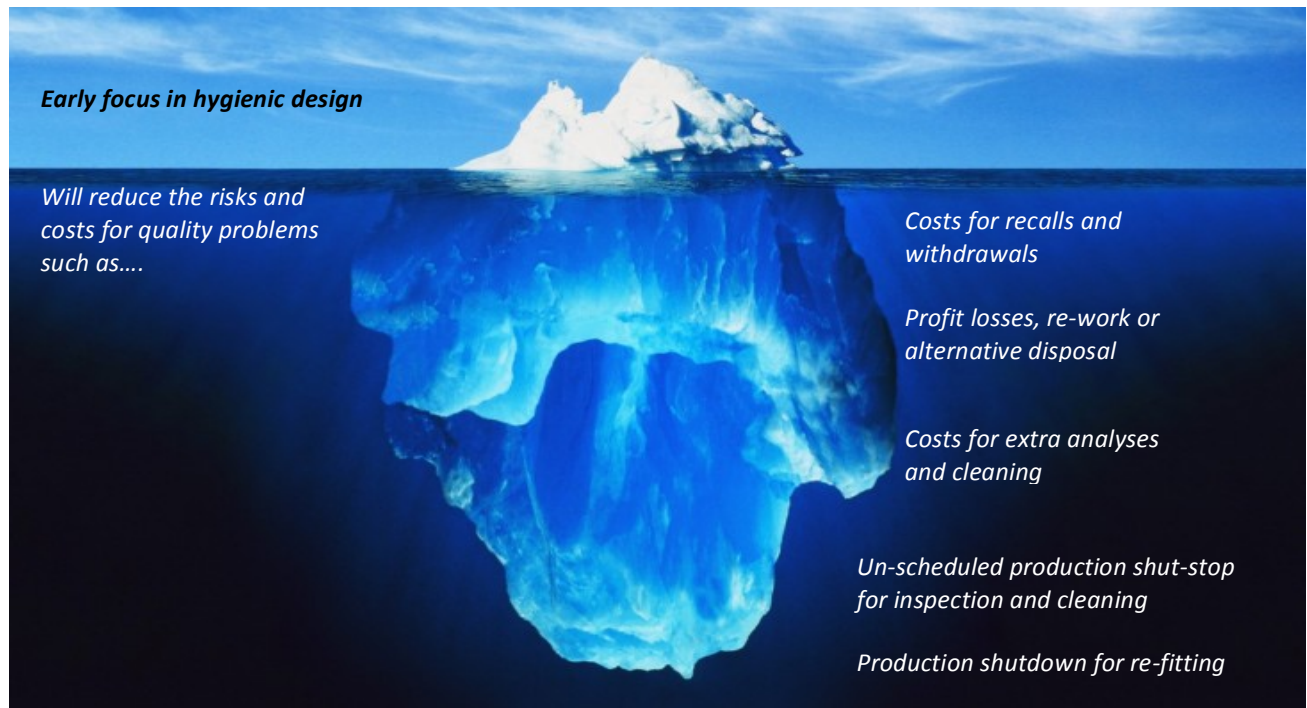
The machinery runs to capacity so the project is delivered and signed off – Hidden problems will often not show during the commissioning phase but requires longer run-time, e.g. build up of biofilm, so it is wise to save the last payment until after a final inspection.

Cleaning is no longer our responsibility it has been outsourced to a third party - It is still your responsibility since you allow for the down time for cleaning, agrees to the chemicals being used, and if something goes wrong it will hit your brand. Remember to have your own cleaning inspections and regular review with the cleaning company.

Project business model and resources

It is well known across all industries that the later in a project a problem is identified and needs attention the more resources are needed to solve this. Early focus in hygienic design in relation to the specific process and product will minimize the risk and costs for quality problems once the equipment has been installed and the process is fully implemented.

As a rule of thumb for each step down the project chain you can multiply the total resources needed with a factor 10 in order to solve a problem. So what might require 10 extra hours in the design phase may require 100-1000 times the resources to re-fit once the equipment is on site or even worse taken into production when adding up the working hours, equipment and spare part costs, product loss and at worst case product recall.



Extra costs for considering quality and safety aspects could be:

- *further assessment of process and product characteristics*
- *process and design review*
- *inspection and validation of equipment before installation*
- *inspection and validation of equipment after 3 and 12 months production*

Costs related to quality problems could be:

- *extra cleaning-time due to build up of biofilm / exceeding microbiological limits*
- *changes to cleaning and Standard Operating Procedures*
- *handling of non-conforming products*
- *extra analyses for product release or product disposal*
- *withdrawal or recall costs*
- *production shut-down for unplanned cleaning / inspection / re-fitting*

It is important to remember that even small compromise may involve high costs in the expected 10-20 years of total life-time of a new production line, therefore it is up to both the equipment and food manufacture to agree on where they wish to spend the resources – by thorough interaction up front or re-fitting and recalls down the line.